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10/553,639

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EXAMINER

BURKHART, MICHAEL D

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

12/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/553,639 | Applicant(s) SAITO ET AL. | |
| | Examiner Michael Burkhart | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5 and 8-36 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11, 13-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 8, 9, 12, 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt and entry of the amendment dated 10/12/2010 is acknowledged. After entry of the amendment, claims 1, 5, 8-36 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Objections

The following objections are made due to poor grammar and spelling, resulting in clumsy and potentially confusing claim language.

Claim 1 is objected to because of the following informalities: "each of said repeats has a complete nucleotide sequence" in line 4 should be "each of said repeats having a complete nucleotide sequence". Appropriate correction is required.

Claim 1, part (6) merely recites an intended use for the claim composition and as such adds very little to no structure to the claimed composition (the restriction sites to be used in part (6) are already recited in claim 1 part (5)). Part (6) does add further confusion to the claimed subject matter due to poor grammar ("by being acted by a restriction enzyme"). Thus, it is suggested part (6) be removed altogether, or be amended such that at least the above phrase is in line with acceptable language.

Claim 8 is objected to because of the following informalities: "gene deletion site is SwaI recognition" in line 3 should be "gene deletion site is a SwaI recognition ". Appropriate correction is required.

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Claim 32 is objected to because of the following informalities: "recognition sequences is Sall recognition or NruI recognition sequence" in lines 2-3 should be "recognition sequences are Sall or NruI recognition sequences". Appropriate correction is required.

Claim 33 is objected to because of the following informalities: "restriction enzyme recognition sequence which is not preset in the" in line 2 should be " restriction enzyme recognition sequences which are not present in the adenoviral genome₂". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 8, 9, 12 and 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection necessitated by amendment of the claims, primarily the addition of claim 1, part (5).**

Claim 1, from which all other claims depend, recites a cosmid vector comprising two "pairs" of identical restriction enzyme recognition sequences (restriction sites) in parts (3) and (5). The recitation of identical pairs "on both sides of the adenoviral genome" in part (3) creates confusion as to how many restriction sites are required to meet the claim limitations: does this require, for example, two tandem EcoRI sites (a pair of identical sites) at the left ITR and a pair of tandem BamHI sites after the right ITR, or can it be EcoRI sites at the left and right ITRs? The recitation of a second pair of identical sites in part (5) further complicates the claim for the same reason, and adds additional confusion as to where in the vector one of these sites must be.

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This is because part (5) recites that one of the sites is present within the E1 deletion and at "a right side of a foreign gene insertion site." Are these two different locations for the same restriction site (typically six base pairs), or are the E1 deletion and insertion site at least adjacent to each other? Since no foreign gene has been inserted in the claimed vector, this limitation also presents antecedent basis issues (part (2) of claim 1 merely recites an intended use of the restriction site, and does not require insertion of a foreign gene). Furthermore, the phrase "within the right side is a IVa2 gene side" is not understood in the least. The Examiner is aware of the IVa2 gene and its placement in the adenoviral genome (basically the 3' region of the E2 gene), but beyond that this limitation is not decipherable. What is a "gene side"? Therefore, the number and placement of the recited pairs of identical restriction sites cannot be determined from the claims, rendering the scope of the claimed subject matter unclear.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633